

**REMARKS/ARGUMENTS**

**Status of the Claims**

Claims 1-12 are pending in the application.

Claims 6-10 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1, 2, 4, and 11-12 are rejected under 35 U.S.C. §112, first paragraph for an allegedly insufficient written description.

Claims 1, 4, and 11-12 are rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement.

Claims 1, 4, and 11-12 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Demchyshyn *et al.* (PNAS USA 91:51558-5162, 1994).

**Support for amendments to the claims**

Support for the amendments to claims 1, 4, and 11 can be found in paragraph 0063 of the published application, wherein it is stated that "The phrase 'substantially identical' in the context of two nucleic acids or polypeptides, refers to two or more sequences... that have... 90-95% ... residue identity".

Support for the amendments to claims 1, 3, 4, 5, and 11 wherein serotonin transporter is substituted for membrane transporter, can be found in the original claims and in the paragraph 0037 of the published application wherein the term "insect cell membrane transporter" is defined.

Support for the amendments to claims 3, and 5 can be found in original claims 1, 3, and 5.

Support for the amendment to claim 12 wherein the mammalian cell is a CV-1 cell is found in paragraph 0176 of the published application.

### **Allowable Subject Matter**

The Examiner has indicated that claims 3 and 5 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

### **The Rejections**

#### **Rejection under 35 U.S.C. §112, first paragraph: written description**

Claims 1, 2, 4, and 11-12 are rejected under 35 U.S.C. §112, first paragraph for an allegedly insufficient written description. The Examiner alleges that the subject matter is not described in such a way as to convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed.

In order to expedite prosecution, claims 1 and 4 recite a polypeptide with greater than about 95% amino acid sequence identity to SEQ ID NO:4. It is well-established that written description is analyzed from the standpoint of the skilled artisan reading the specification. *See, e.g., Wang Labs v. Toshiba Corp.*, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993). Thus, "an inventor is not required to describe every detail of his invention," and a disclosure "is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out." *See* MPEP § 2163 II(A)(3)(a)(i), *citing In re Hayes Microcomputer Products, Inc. Patent Litigation*, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992).

One of skill in the art would recognize that a small percentage of changes to an amino acid sequence, such as the conservatively modified variants disclosed in paragraph 0047 of the published application, should not result in any change in activity of a polypeptide. Similarly, alleles, and polymorphic variants may differ slightly from a sequence such as SEQ ID NO:4, yet still retain the same functional properties. Thus, disclosure of a sequence with 95% sequence identity to SEQ ID NO:4 and the functional properties of a serotonin transporter would be sufficient for one of skill to recognize that the inventors had possession of the claimed invention at the time the application was filed.

In addition to an amino acid sequence, the Applicants have also provided an assay for measuring the activity of a serotonin transporter (*see e.g.*, paragraph 0176 of the published application). Thus, the Applicants have provided an assay to determine the activity of sequences 95% identical to SEQ ID NO:4. Therefore, one of skill would recognize SEQ ID NO:4 as a representative example the genus encompassed by a claim to 95% amino acid sequence identity since the Applicants have disclosed a correlation between structure and function that demonstrates that they indeed had possession of the claimed invention.

As currently written, claims 2 and 11 recite a nucleic acid encoding a polypeptide comprising SEQ ID NO:4. As is known in the art and disclosed in paragraph 0046 of the published application, because of the degeneracy of the genetic code, a large number of nucleic acids may encode identical protein sequences. Indeed, disclosure of an amino acid sequence provides sufficient information such that one would accept that that Applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence (MPEP 2163II.(A)(3)(a)(ii)). Thus, SEQ ID NO:4 is a representative example of the genus disclosed in claims 2 and 11.

**Rejection under 35 U.S.C. §112, first paragraph: enablement**

Claims 1, 4, and 11-12 are rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement.

As currently written claims 1, 4, and 11-12 recite a polypeptide with greater than about 95% amino acid sequence identity to SEQ ID NO:4. The Examiner has provided no reasoning or evidence to show that undue experimentation would be required to make all of the nucleic acid sequences encompassed by the scope of the invention. Furthermore, as discussed above, one of skill in the art could easily recognize an amino acid sequence with 95% sequence identity to SEQ ID NO:4, that exhibits serotonin transporter activity as defined by the functional assay for serotonin transport disclosed in paragraph 0176 of the published application, is in fact a serotonin transporter.

Everything necessary to practice the invention need not be disclosed for an invention to be enabled for its full scope (MPEP 2164.08). Indeed, all that is necessary is that

one skilled in the art be able to practice the invention, given the level of knowledge and skill in the art (MPEP 2164.08). Thus, the claims to 95% sequence identity when coupled with a functional assay for serotonin transporter activity, provides an enabling disclosure because one of skill in the art could readily make all the variants encompassed by the scope of the claims, and could easily determine the activity of the claimed variants.

**Rejection under 35 U.S.C. §102(b)**

Claims 1, 4, and 11-12 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Demchyshyn *et al.* (PNAS USA 91:51558-5162, 1994).

The Examiner states that Demchyshyn *et al.* disclose a serotonin transporter from *Drosophila melanogaster* which is 74.3% identical to SEQ ID NO:4.

Claims 1, 4, and 11 have been amended to recite 95% sequence identity, thereby obviating the rejection.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

  
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